

Claims:

- 1 1. A calcium salt of rabeprazole.
- 1 2. The salt of claim 1, which is rabeprazole hemicalcium.
- 1 3. The salt of claim 1 or 2, which is in a crystalline form.
- 1 4. The salt of claim 3, which is an alcohol solvate.
- 1 5. The salt of claim 4, which is a methanol solvate.
- 1 6. The salt of claim 1 or 2, which is in a substantially amorphous form.
- 1 7. The salt of claim 1 or 2, which is hydrated.
- 1 8. The crystalline form of rabeprazole calcium of claim 3, wherein the rabeprazole
2 calcium has the X-ray diffraction pattern of Figure 1.
- 1 9. The crystalline form of rabeprazole calcium of claim 3, wherein the rabeprazole
2 calcium has the infrared spectrum of Figure 2.
- 1 10. The amorphous form of rabeprazole calcium of claim 6, wherein the rabeprazole
2 calcium has the X-ray diffraction pattern of Figure 4.
- 1 11. The amorphous form of rabeprazole calcium of claim 6, wherein the rabeprazole
2 calcium has the infrared spectrum of Figure 5.
- 1 12. A pharmaceutical composition comprising:
2 a therapeutically effective amount of rabeprazole calcium; and one or more pharmaceutically
3 acceptable carriers, excipients or diluents.
- 1 13. A process for the preparation of rabeprazole calcium, the process comprising:
2 contacting rabeprazole free base or rabeprazole sodium with a calcium salt of an acid in a
3 suitable solvent; and
4 isolating the rabeprazole calcium from the solution thereof by the removal of the solvent.
- 1 14. The process of claim 13, wherein the calcium salt of an acid is a salt of an inorganic acid.
- 1 15. The process of claim 14, wherein the calcium salt comprises one or more of calcium
2 chloride, calcium nitrate, calcium sulphate, calcium phosphate, calcium carbonate, and calcium
3 dihydrogenphosphate.
- 1 16. The process of claim 13, wherein the calcium salt of an acid is a salt of an organic acid.

- 1 17. The process of claim 16, wherein the calcium salt comprises one or more of calcium
2 oxalate, calcium acetate, calcium lactate, calcium succinate, calcium citrate, and calcium
3 tartrate.
- 1 18. The process of claims 13, wherein the solvent comprises one or more of water, lower
2 alkanol, ketone, ester, ether, nitrile, hydrocarbon, dipolar aprotic solvent, or mixtures thereof.
- 1 19. The process of claim 18, wherein the the lower alkanol comprises one or more of
2 primary, secondary and tertiary alcohol having from one to six carbon atoms.
- 1 20. The process of claim 19, wherein the lower alkanol comprises one or more of
2 methanol, ethanol, denatured spirit, n-propanol, isopropanol, n-butanol, isobutanol, and t-
3 butanol.
- 1 21. The process of claim 20, wherein the lower alkanol comprises one or more of
2 methanol, ethanol, and isopropanol.
- 1 22. The process of claim 18, wherein the ketone comprises one or more of acetone,
2 2-butanone, and 4-methylpentan-2-one.
- 1 23. The process of claim 18, wherein the ester comprises one or more of methyl acetate,
2 ethyl acetate and isopropyl acetate.
- 1 24. The process of claim 18, wherein the nitrile is acetonitrile.
- 1 25. The process of claim 18, wherein the ether comprises one or more of dioxane and
2 tetrahydrofuran.
- 1 26. The process of claim 18, wherein the hydrocarbon comprises one or more of hexane
2 and toluene.
- 1 27. The process of claim 18, wherein the dipolar aprotic solvent comprises one or more of
2 dimethylsulfoxide and dimethylformamide..
- 1 28. The process of claim 13, further comprising adding a base if rabeprazole free base is
2 used as a starting material.
- 3 29. The process of claim 28, wherein the base comprises one or more of an alkali metal
4 hydroxide, alkali metal carbonate and alkali metal bicarbonate.

- 1 30. The process of claim 29, wherein the base comprises one or more of sodium hydroxide,
2 potassium hydroxide, sodium carbonate, potassium carbonate and sodium bicarbonate.
- 1 31. The process of claim 13, wherein the rabeprazole calcium precipitates out
2 spontaneously from the solvent.
- 1 32. The process of claim 13, wherein removing the solvent comprises one or more of
2 filtration, filtration under vacuum, decantation, and centrifugation.
- 1 33. The process of claim 13, wherein rabeprazole hemicalcium is isolated from the solution.
- 1 34. The process of claim 13, wherein a crystalline form of rabeprazole calcium is isolated
2 from the solution.
- 1 35. The process of claim 34, wherein an alcohol solvate is isolated from the solution.
- 1 36. The process of claim 35, wherein a methanol solvate is isolated from the solution.
- 1 37. The process of claim 13, wherein a substantially amorphous form of rabeprazole calcium
2 is isolated from the solution.
- 1 38. The process of claim 13, wherein the hydrate of rabeprazole calcium is isolated from the
2 solution.
- 1 39. The process of claim 13, further comprising additional drying of the product obtained.
- 1 40. The process of claim 13, further comprising forming the product obtained into a
2 finished dosage form.
- 3 41. The process of claim 13, wherein the rabeprazole calcium has the X-ray diffraction
4 pattern of Figure 1.
- 1 42. The process of claim 13, wherein the rabeprazole calcium has the infrared spectrum of
2 Figure 2.
- 3 43. The process of claim 13, wherein the rabeprazole calcium has the X-ray diffraction
4 pattern of Figure 4.
- 1 44. The process of claim 13, wherein the rabeprazole calcium has the infrared spectrum of
2 Figure 5.
- 1 45. A method for treating or preventing gastrointestinal ulcers, which comprises
2 administering to a patient in need thereof an effective amount of rabeprazole calcium.

- 1 46. The method of claim 45, wherein the rabeprazole calcium is used for healing of erosive
2 or ulcerative gastroesophageal reflux disease (GERD); maintenance of healing of erosive or
3 ulcerative GERD; healing of duodenal ulcer; or treatment of pathological hypersecretory
4 conditions, including Zollinger-Ellison Syndrome.
- 1 47. The method of claim 45, or 46, wherein the rabeprazole calcium is rabeprazole
2 hemicalcium.
- 1 48. A pharmaceutical composition for use in the treatment or prevention of gastrointestinal
2 ulcers comprising an effective amount of rabeprazole calcium and pharmaceutically acceptable
3 excipients.
- 1 49. The pharmaceutical composition of claim 48, wherein the rabeprazole calcium is
2 rabeprazole hemicalcium.
- 1 50. The pharmaceutical composition of claim 48, or 49, wherein a crystalline form of the
2 rabeprazole calcium is used.
- 1 51. The pharmaceutical composition of claim 48, or 49, wherein an alcohol solvate of the
2 rabeprazole calcium is used.
- 1 52. The pharmaceutical composition of claim 48, or 49, wherein a substantially amorphous
2 form of the rabeprazole calcium is used.
- 1 53. The pharmaceutical composition of claim 48, or 49, wherein a hydrate of the rabeprazole
2 calcium is used.